

5774-01-MR
Application No. 09/674,819

REMARKS

I. Status of the Application

This submission, which accompanies a Request for Continued Examination, amends claims 1-17, 20, and 21, and adds new claims 22-27. As originally filed, the application included claims 1-17. In response to a Restriction Requirement mailed August 29, 2001, Applicant amended claims 1 and 12 and added claims 18 and 19. In response to an Office Action mailed February 6, 2002, which rejected all of the claims, Applicant amended claim 12, canceled claims 18 and 19, and added claims 20 and 21. A subsequent Final Office Action, which was mailed on November 1, 2002, maintained the rejection of claims 1-17, and rejected newly added claims 20 and 21. Accordingly, claims 1-17 and 20-27 are under currently under consideration in the present application.

By action taken here, Applicant in no way intends to surrender any range of equivalents beyond that needed to patentably distinguish the claimed invention as a whole over the prior art. Applicant expressly reserves all such equivalents that may fall in the range between Applicant's literal claim recitations and combinations taught or suggested by the prior art.

II. Amendment of Claims 1-17, 20, and 21

The present application amends independent claims 1 and 12 so they each recite a "stabilizer," which is a "humectant" that is "effective against degradation of the 4-amino-3-substituted-butanoic acid derivative due to lactam formation." Dependent claims 2-11, 13-17, 20, and 21 were amended to ensure consistency with changes made to the independent claims and to correct grammar and spelling. In addition, claims 2 and 13 were amended to recite a "lower aliphatic acid ester of glycerol." The specification, as filed, fully supports the changes to the claims and therefore Applicant submits that the amendment of claims 1-17, 20, and 21 introduces no new matter. See, for example, Application at page 5, lines 12-23, and page 35, lines 1-10.

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III. New Claims 22-27

Applicant has added new claims 22-27. These claims are similar to claims 1, 2, 4, 12, and 13, except they recite a particular 4-amino-3-substituted-butanoic acid derivative, namely, gabapentin. The specification, as filed, fully supports these new claims, and therefore Applicant submits that claims 22-27 introduce no new matter. See, for example, Application at page 5, lines 12-23; page 34, lines 2-9; and page 35, lines 1-10.

IV. Rejection of Claims Under 35 U.S.C. § 103(a)

The Final Office Action rejected claims 1-17, 20, and 21 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,025,035 to Wallace, U.S. Patent No. 5,084,479 to Woodruff, European Patent No. 458,751, or abstract of Japanese Patent No 63253022. According to the Final Office Action:

Wallace and Woodruff disclose pharmaceutical compositions of gabapentin and other 4-amino-3-substituted-butanoic acid derivatives with applicant's preferred humectants propylene glycol, glycerin, and sorbitol; see col. 2, lines 13-57 of Wallace and col. 3, line 35 to col. 4, line 12 of Woodruff in particular. European Patent 458,751 discloses compositions of gabapentin and related compounds with excipients including sorbitol, monoglycerides, diglycerides, and triglycerides; see page 4, line 55 to page 5, line 51. The Japanese patent abstract discloses compositions of applicant's preferred compound baclofen with propylene glycol as an excipient. Some claims differ in that they require humectants such as ethylene and butylene glycol which are not taught by the prior art. However, since these are conventional humectants in the pharmaceutical arts, it would have been obvious to one skilled in the art to employ them in the claimed compositions. The claimed amounts are obvious since it is within the skill of the pharmaceutical artisan to determine the amount of drug that provides the therapeutic effect most effective for treating the patient's condition while minimizing adverse side effects.

Final Office Action at page 2. Applicant respectfully traverses the rejection in view of the above amendments, the remarks that accompanied Applicant's amendment filed on August 6, 2002, and the following comments.

As indicated above, Applicant has amended the claims so that they recite the use of a "stabilizer," which is a "humectant" and is "effective against degradation of the 4-amino-3-substituted-butanoic acid derivative due to lactam formation." Applicant

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submits that none of the cited prior art references, either alone or in combination, teach or suggest a solid composition that includes a humectant that stabilizes the recited 4-amino-3-substituted-butanoic acid derivatives against degradation resulting from lactam formation. Three of the prior art references applied in the Final Office Action—including the Japanese Patent abstract and the patents to Wallace and Woodruff—do not discuss the stability of the recited 4-amino-3-substituted-butanoic acid derivatives. Although European Patent 458,751 discloses that gabapentin can degrade because of lactam formation, the reference does not teach or suggest the use of a humectant to stabilize gabapentin against lactam formation.

Moreover, the Final Office Action supports Applicant's contention that the cited prior art neither teaches nor suggests the use of a humectant to stabilize the recited 4-amino-3-substituted-butanoic acid derivatives:

Although none of the prior art references specifically suggest the stabilizing effect or avoidance of degradation by using a humectant, the references clearly teach that many of the claimed humectants are appropriate carriers for the claimed compounds. It is not necessary that the prior art teach the intended purpose of the humectant (i.e., to manufacture small, stabilized compositions containing high concentrations of active ingredients) to make the claim obvious.

Final Office Action at page 2. Though it may not be necessary that the cited prior art teach the intended purpose of the humectant, it is necessary that the prior art teach every claim limitation. Since the claims recite a "stabilizer," which is a "humectant and effective against degradation of the 4-amino-3-substituted-butanoic acid derivative due to lactam formation," Applicant submits that the cited prior art cannot render the claims obvious.

V. Conclusion

In view of the foregoing, Applicant respectfully submits that all pending claims are patentable over the prior art of record. If the Examiner has any questions, Applicant requests that the Examiner telephone the undersigned.

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Applicant believes that any fees associated with the filing of the present amendment have been identified in a transmittal that accompanies this paper. However, if any fees are required in connection with the filing of this paper, and such fees have not been identified in the accompanying transmittal, please charge deposit account number 23-0455.

Respectfully submitted,

Date: April 30, 2003



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